

REMARKS

Favorable and prompt allowance of the pending claims in the application is respectfully requested on the basis of the following particulars.

It is respectfully submitted that no new issues requiring further detailed consideration or search have been presented by the proposed amendments and that entry of the claim amendments is appropriate under 37 C.F.R. § 1.116. Entry of the amendment at least for purposes of appeal is respectfully requested in view of the fact that they present rejected claims in better form for consideration on appeal (37 C.F.R. 1.116).

1. In the specification

The specification is amended to describe Fig. 17 with the statement that the “proximal surface of the facing layer 12 and the skin adherent adhesive or elastomeric gel of the border portion 45 of the backing layer 16 lie along the same plane and are thereby co-planar.”

No new matter is introduced by the amendment to the specification since support for this statement is readily apparent from the depiction of the embodiment in originally-filed Fig. 17.

Entry of the amendment to the specification is kindly requested.

2. In the claims

In the AMENDMENT TO THE CLAIMS, independent claim 12 is amended by the removal of the term “generally.” This amendment does not raise new issues requiring further searching in that it is clear from the examiner’s comments on page 3 of the action that the term “generally” or the absence thereof in connection with the term “co-planar” has already been considered when interpreting the scope of claim 12.

Claim 22 is cancelled without prejudice or disclaimer so as to simplify issues of this application should the applicant chose to appeal this final rejection.

It is submitted that the amendment to the claims does not introduce new matter into the application. Entry of the amendment to the claims is respectfully requested in the next Office communication.

3. Rejection of claims 12, 14-16 and 18-20 under 35 U.S.C. § 102(e) as being anticipated by U.S. patent application publication 2002/0156410 (*Lawry*)

Reconsideration of the rejection of the claims is courteously requested in view of the amendment to the claims and the following remarks.

In the new rejection, the examiner contends that *Lawry* discloses first and second facing layers that are co-planar. The applicant respectfully disagrees.

Claim 12 has been amended to remove the distinction that the recited first and second facing layers are “generally” co-planar. This claim now recites that the first and second facing layers are simply “co-planar.” In response to the examiner’s assertion that the specification doesn’t explain what is meant by the term “co-planar,” the applicant contends that the specification must not particularly explain what the term “co-planar” means. “Co-planar” is widely understood as having a definition which means “lying or acting in the same plane.” For further reference, the examiner is directed to the following link: <http://www.merriam-webster.com/dictionary/co-planar>.

The depiction of the wound dressing embodiment of Fig. 17 reinforces this ordinary understanding of the term “co-planar” by clearly showing the proximal surfaces of the facing layer (12) and the skin adherent adhesive or elastomeric gel of the border portion (45) of the backing layer (16) located along the same plane. From Fig. 17, the skilled person can discern that there is little or no deviation of the proximal surfaces as lying outside the same plane.

Turning to *Lawry*, it is clear in the cross-sectional views of Figs. 2-5 that the adhesive layer (26) is not arranged along the same plane as the silicone gel layer (16). The rejection appears to reason that the adhesive layer (26) is approximately along the same plane as the silicone gel layer (16), but such reasoning is misplaced since it clearly does not equate to being co-planar.

It is clear in each embodiment in *Lawry* that the silicone gel layer (16) is spaced from the adhesive layer (26) by an intermediate absorbing layer, either by gauze (14) or a thin foam pad (32). The skilled person would readily recognize that the silicone gel layer (16) cannot have a bodyside surface that lies along the same plane as a bodyside surface of the adhesive layer (26) since *Lawry* clearly teaches that the silicone gel layer (16) is to be spaced apart from the adhesive layer (26) by an intermediate absorbing layer.

There is no disclosure or suggestion in *Lawry* in which the skilled person would understand to dispense with the intermediate absorbing layer.

Accordingly, *Lawry* does not and cannot be relied upon to disclose or suggest first and second facing layers having proximal surfaces which are co-planar with one another.

Next, the applicant respectfully requests the examiner to explain how gauze can define a grid of through-extending apertures. Indeed, the skilled person would not understand that gauze includes through-extending apertures. If the gauze (14) had through extending apertures, of which there is no understanding in the description in *Lawry*, the wound exudate would likely travel directly to the backing sheet (12) and absorption of such wound exudate would be hampered.

A grid pattern is accorded its ordinary meaning of a network of uniformly spaced horizontal and perpendicular lines (see <http://www.merriam-webster.com/dictionary/grid>).

*Lawry* provides no understanding of gauze having a grid pattern of through extending apertures, and therefore cannot be relied on this point in the rejection.

Lastly, it is submitted that *Lawry* does not disclose or suggest a silicone gel compound layer that has non-apertured regions consisting the silicone gel compound.

*Lawry* discloses that the gauze is impregnated with the silicone gel. The skilled person would understand that a gel layer being impregnated on a gauze or foam has a thickness that includes portions of the gauze or foam in order to assure that the silicone gel interlocks with the gauze or foam. In other words, the thickness of the impregnating gel layer cannot have a thickness that consists the silicone gel.

It is submitted that the impregnating silicone gel layer of *Lawry* includes portions of either the impregnated gauze (embodiments of Figs. 1-4) or foam (embodiment of Fig. 5). It follows that if the thickness of the silicone gel layer of *Lawry* does not include portions of either the gauze or foam, it cannot remain secured to the gauze or foam since there is nothing that the silicone gel can lock to.

*Lawry* provides no understanding of securing the silicone gel on the gauze or foam in any manner other than by impregnation, and it is established that impregnation of a substrate cannot yield the second facing layer structure of the type required by claim 12.

From these observations, it is submitted that *Lawry* fails to disclose or suggest every limitation required by claim 12. Claims 14-16 and 18-20 are allowable based on their dependency from claim 12 and their individual limitations.

Accordingly, withdrawal of this rejection is respectfully requested.

4. Rejection of claim 22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent application publication 2002/0156410 (*Lawry*)

This rejection is moot in view of the cancellation of claim 22.

5. Rejection of claim 23 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent application publication 2002/0156410 (*Lawry*) in view of U.S. patent application publication 2003/0120229 (*de Jong*)

Reconsideration of this rejection is respectfully requested on the basis of the following observations.

In the action, the same rationale used for rejecting claim 12 is used to reject claim 23 with the exception of the specific limitations that apertures of the facing layer are formed irrespective of the proximal surface of the absorbent core. It is noted, however, that the same rationale used for rejecting claim 12 cannot be used since claim 23 specifically requires a single facing layer which extends across both the absorbent core and a surface of the backing layer.

It is submitted that there is no understanding in *Lawry* of a single silicone gel based facing layer which continuously extends along and is directly bonded to both proximal surfaces of an absorbent core and backing layer.

Obviously the single facing layer of claim 23 is substantially different from the combination of the adhesive layer (26) and the silicone gel layer (16), which are distinct layers formed from dissimilar materials having different adherency properties.

It is readily apparent that the wound dressing of *Lawry* cannot be interpreted as teaching a silicone gel facing layer with a plurality of apertures that are formed irrespective of the proximal surface of the gauze or foam. As acknowledged in the applicant's specification, it was known to impregnate foam with a silicone gel at the time of the present invention (page 4, 2<sup>nd</sup> full paragraph).

An example of impregnating a textile with a silicone gel is found in U.S. patent 4,838,253 (*Brassington*) wherein it is explained in Col. 4, line 64 through Col. 5, line 8 that the silicone gel "encapsulates" the fibers of a non-woven or woven or cotton gauze. Clearly, from *Brassington*, the silicone gel facing layer cannot have non-apertured regions consisting the silicone gel; the non-apertured regions clearly include fibers from the substrate. Moreover, the apertures are also formed on the basis of the geometrical structure of the substrate upon which the silicone gel is coated. Therefore, the apertures are not formed in the facing layer irrespective of the substrate.

An example of coating foam with a silicone gel is found in U.S. patent 6,051,757 (*Lindqvist*). In this reference, however, the apertures in the silicone gel layer are formed by capillary action when impregnation is used which in turn closes some of the pores of the foam and forms a random apertured structure in the facing layer. Thus, from *Lindqvist*, the silicone gel facing layer cannot have non-apertured regions consisting the silicone gel; the non-apertured regions clearly include portions of the foam. Moreover, the apertures are also formed on the basis of the geometrical structure of the foam upon which the silicone gel is coated. Therefore, the apertures are not formed in the facing layer irrespective of the foam.

In view of the evidence in the applicant's specification, the evidence in the teachings of *Brassington* and *Lindqvist* in the prior art, and the absence of any such guidance in *Lawry*, it is submitted that it was not known at the time of the invention to provide a wound dressing wherein apertures of a facing layer are formed irrespective of the proximal surface of an absorbent core.

The applicant points out that the silicone gel layer in claim 23 is not impregnated onto the absorbent core, and the silicone gel layer of claim 23 is formed consistently with any one of the possible methods of the specification. As explained on page 22, 1<sup>st</sup> full paragraph of the specification, the silicone gel layer is formed as a silicone gel sheet having a pattern of apertures that are formed prior to the silicone gel sheet being bonded to the absorbent core. This crucial step distinguishes the inventive wound dressing over the teachings of *Lawry*, *Brassington* and *Lindqvist* since those documents effectively teach coating a substrate with a very thin layer (e.g., see *Lawry* at paragraph [0029] describing thickness of silicone gel sheet at 0.05 inch to about 0.3 inch) of uncured gel over such substrate and forming apertures as a basis of the substrate, i.e., capillary action.

As discussed in the 2<sup>nd</sup> full paragraph on page 22 of the specification, the silicone gel layer may be substantially planar along the proximal surface. A discussion of the various methods for forming the facing layer in the manner described above is provided by way of Figs. 19-24 and corresponding sections in the specification.

It is submitted from this evidence provided in the applicant's specification that the skilled person would not have a reasonable expectation of success of forming apertures in the silicone gel layer irrespective of the surface of the gauze or foam of the wound dressing in *Lawry*, or by other prior art. The silicone gel layer of *Lawry* and other prior art documents is impregnated into gauze or foam, and is therefore dependent on the structure of the gauze or foam for the formation of apertures formed therein.

From these observations, the applicant has shown that impregnating silicone gel on a gauze or foam surface does not yield a silicone gel layer which has apertures

formed irrespective of the proximal surface of absorbent core, and that the prior art does not disclose a silicone gel based facing layer having non-apertured regions consisting a silicone gel compound while still being directly bonded to an absorbent core.

Hence, the silicone gel facing layer of claim 23 has a structure which precludes facing layers formed by way of impregnation of a substrate.

As for *de Jong*, it is clear that *de Jong* fails to make up for the shortcomings of *Lawry* on the basis that *de Jong* does not provide any discussion on a silicone gel compound facing layer.

Accordingly, the combination of *Lawry* and *de Jong* fails to disclose or suggest every feature required by claim 23. Withdrawal of this rejection is kindly requested.

6. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicants' attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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Respectfully submitted,

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